

ALLEGED SHIPMENT: On or about February 3 and 6, 1946, from the State of New Jersey into the States of Maryland and Michigan.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they purported and were represented to possess, in that there was less ephedrine hydrochloride in the *P-Drine Sulfathiazole*, less alcohol and ferrous sulfate in the *Elixir Feotone*, less desoxyephedrine hydrochloride in the *Sulfedol*, and less ephedrine alkaloid in the *isotonic solution ephedrine gluconate* and the *isotonic ephedrine solution* than the respective articles were represented to contain.

Misbranding, Section 502 (a), the following label statements were false and misleading: (*P-Drine Sulfathiazole*) "Ephedrine Hydrochloride 1 Percent," (*Elixir Feotone*) "Each fluid ounce contains Alcohol 5%, Ferrous Sulfate—20 Grains," (*Sulfedol*) "Desoxyephedrine Hydrochloride 0.125%," and (*isotonic solution ephedrine gluconate* and *isotonic ephedrine solution*) "Contains Ephedrine Alkaloid 1%."

DISPOSITION: June 6, 1947. A plea of guilty having been entered, the court imposed a fine of \$5 on each of the 10 counts of the information.

2207. Adulteration of thiamine hydrochloride tablets. U. S. v. Rexall Drug Co. (United-Rexall Drug Co.). Plea of nolo contendere Fine, \$1,500
(F. D. C. No. 23279. Sample Nos. 62901-H, 62902-H, 81514-H.)

INFORMATION FILED: August 12, 1947, Eastern District of Missouri, against the Rexall Drug Co., a corporation, formerly trading as United-Rexall Drug Co., St. Louis, Mo.

ALLEGED SHIPMENT: Between the approximate dates of November 7, 1945, and June 21, 1946, from the State of Missouri into the States of California and Oregon.

LABEL, IN PART: "Thiamine Hydrochloride (Vitamin B₁) United Drug Co. Boston—St. Louis."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article was represented as a drug, the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality fell below the official standard since it contained glass.

DISPOSITION: September 29, 1947. A plea of nolo contendere having been entered, the court imposed a fine of \$500 on each of the 3 counts of the information.

2208. Adulteration of physiological salt solution. U. S. v. 178 Vials * * *
(F. D. C. No. 23501. Sample No. 87813-H.)

LIBEL FILED: July 17, 1947, District of New Jersey.

ALLEGED SHIPMENT: On or about June 12, 1947, by the Gotham Pharmaceutical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 178 vials of *physiological salt solution* at Hoboken, N. J.

LABEL, IN PART: "100 cc. Size Sterile Physiological Salt Solution * * * Parenteral."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Physiological Salt Solution for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: September 9, 1947. Default decree of condemnation and destruction.

2209. Adulteration of epinephrine hydrochloride injection. U. S. v. 120 Vials * * *
(F. D. C. 23691. Sample No. 66340-H.)

LIBEL FILED: September 9, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 18, 1947, by Lederle Laboratories Division, American Cyanamide Co. (Shipment made from Pearl River, N. Y.)

PRODUCT: 120 1-ounce vials of *epinephrine hydrochloride injection* at Norristown, Pa.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Epinephrine Hydrochloride Injection," a drug the

name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: October 13, 1947. Default decree of condemnation and destruction.

2210. Adulteration of water for injection. U. S. v. 2,476 Vials * * *.
(F. D. C. No. 22743. Sample No. 66307-H.)

LABEL FILED: March 27, 1947, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about January 14 and February 1 and 19, 1947, by Vitamin Corporation of America, from Newark, N. J.

PRODUCT: 2,476 100-cc. vials of *water for injection* at Philadelphia, Pa.

LABEL, IN PART: "Water for Injection or Parenteral Use as a Vehicle or Diluent."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth in that compendium since the article was contaminated with undissolved material.

DISPOSITION: April 22, 1947. No claimant having appeared, judgment of condemnation was entered. It was ordered that the product be destroyed and that the glass vials and rubber stoppers be retained by the shipper after the destruction of the contents.

2211. Adulteration and misbranding of uargin tablets. U. S. v. 25 Bottles, etc.
(F. D. C. No. 23162. Sample No. 83102-H.)

LABEL FILED: June 2, 1947, Western District of Kentucky.

ALLEGED SHIPMENT: On or about March 3, 1947, by the Grisard Laboratories, Inc., from Winchester, Tenn.

PRODUCT: 25 bottles and 26 bottles, each bottle containing 100 tablets, of *uargin tablets* at Louisville, Ky.

LABEL, IN PART: (Bottle) "Uargin, Contains two of the cardio-active glycosides of squill * * * Standardized by the U. S. P. XII Cat Method, Each Tablet * * * equivalent to 2.5 Cat Units. * * * Assayed Biologically"; (circular) Standardized by the physical method of optical rotation; by chemical analysis; and by biological assay using the cat method of Hatcher and Brody."

NATURE OF CHARGE: Adulteration, Section 501 (b), the strength of the article differed from that which it was represented to possess, in that each tablet was represented to be equivalent to 2.5 cat units, whereas when subjected to bio-assay, each tablet was found to possess not more than 1.55 cat units per tablet, or not over 62 percent of the strength declared on the label.

Misbranding, Section 502 (a), the label statement "Standardized by the U. S. P. XII Cat Method" was misleading. The statement suggested, implied, and created the impression that the article is recognized in the United States Pharmacopoeia, Twelfth Revision, whereas it is not recognized in the Pharmacopoeia.

DISPOSITION: August 29, 1947. Default decree of condemnation and destruction.

2212. Adulteration of burdock root. U. S. v. 14 Bags * * *. (F. D. C. No. 22512. Sample No. 81409-H.)

LABEL FILED: February 11, 1947, District of Oregon.

ALLEGED SHIPMENT: On or about October 22, 1946, by Dan S. Carroll, from Vernal, Utah.

PRODUCT: 14 bags, containing approximately 404 pounds, of *burdock root* at Portland, Oreg.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Burdock Root," a drug the name of which is recognized in the National Formulary, an official compendium, but its quality and purity fell below the official standard since it was moldy.

DISPOSITION: April 11, 1947. Default decree of condemnation and destruction.